

# Importance of an Analytical Database for Dietary Supplements in the Assessment of Nutrient Intake

Agricultural Research Service

Cuiwei Zhao<sup>1</sup>, Amy L Schweitzer<sup>1</sup>, Karen W Andrews<sup>1</sup>, Janet Roseland<sup>1</sup>, Joanne M Holden<sup>1</sup>, Charles Perry<sup>1</sup>, James Harnly<sup>2</sup>, Wayne Wolf<sup>2</sup>, Johanna T Dwyer<sup>3</sup>, Mary Frances Picciano<sup>3</sup>, Joseph M Betz<sup>3</sup>, Leila G Saldanha<sup>3</sup>, Elizabeth Yetley<sup>3</sup> Kenneth Fisher<sup>3</sup>, Kathy Radimer<sup>4</sup>, Jamie Wilger<sup>4</sup>, Kathy Sharpless<sup>5</sup>

<sup>1</sup> Nutrient Data Lab, <sup>2</sup> Food Composition Lab, United States Department of Agriculture (USDA), <sup>3</sup> Office of Dietary Supplements (ODS), National Institutes of Health, <sup>4</sup> National Center for Health Statistics, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services <sup>5</sup>National Institute of Standards and Technology

#### **Abstract**

A dietary supplement nutrient composition database is needed to support research studies investigating the links between cancer and dietary intake of food and supplements. The USDA Nutrient Data Laboratory and the Food Composition Laboratory of USDA, the Office of Dietary Supplements, the National Center for Health Statistics (NCHS) and National Institute of Standards and Technology (NIST) are collaborating to develop an analytically validated Dietary Supplement Ingredient Database (DSID), in conjunction with the dietary supplement label database maintained by NCHS. This study reports the evaluation of the relationship between nutrient content values indicated on labels of multivitamin/mineral (MVM) products and the actual analytical values for nutrients in these products. In this study, we used NHANES 2001-2002 data on reported frequency of MVM intake of adults and nutrient content data from MVM labels for Vitamin D and 22 other vitamins and minerals. In the NHANES survey, about 1800 adult respondents representing about 35% of the US adult population, reported taking at least one MVM product during the previous month. A total of 1726 respondents, representing 29% of US adults, took a vitamin D-containing MVM. The total number of supplements taken was 2,200 with about 540 MVM adult products (24%). Of these, 349 products contained Vitamin D, in most cases as ergocalciferol (D2), ranging from 5% to 250% DV (20 International Units (IU) to 1000 IU). Among these adult MVM, the common levels of vitamin D in rank order were 100, 50 and 62.5 % Daily Value (DV); however, the most commonly reported single level for most other nutrients was 100% DV. To validate the composition of MVM products, a pilot study to determine levels of 23 nutrients was conducted. The results indicated that most nutrients (16) had <10 % coefficient of variation (CV). However, a few nutrients including Vitamin D, showed variability higher than 20% CV, Validation of dietary supplement composition is necessary for accurate assessment of total intake of Vitamin D and other nutrients from dietary supplements and food and their effects on health status.

# **Objectives**

 To assess common nutrient % Daily Value (DV) levels and their frequency of use for Vitamin D and 22 other nutrients in adult MVM reported in NHANES 01-02

•To identify representative products in order to evaluate the systematic relationship between label value and analyzed value for nutrients in adult MVM

•To evaluate a uniform protocol of sample handling, analytical methodologies and laboratory variability for Vitamin D and 22 other nutrients in MVM products to assess the laboratory coefficients of variation as a prelude to a larger study of nutrient composition of dietary supplements

## Introduction

Nutrient label values and information about the frequency of intake of specific dietary supplements were obtained from the NHANES (1). The DSID working group prioritized supplement nutrients using a series of weighted factors, including exposure, research interest, measurement capabilities and public health importance (2). Vitamin D and 22 other nutrients were the high priority nutrients for evaluation.

A pilot study assessing sample handling, analytical methods and laboratory variability for these 23 nutrients provided valuable information for subsequent studies. In the current study, we analyzed data on label values for Vitamin D and 22 other vitamins and minerals in adult MVM products and the reported weighted frequency of use from NHANES 01-02 data. The two, three or four most common %DV levels were selected for each nutrient, in order to assess the relationship between reported label value and actual analytically determined value. (Daily Value is the recommended daily amount based on a 2000-calorie diet.) 1. http://www.cdc.gov/nchs/nhanes/accessed May 2005

2 Johanna T. Dwyer, Mary Frances Picciano, Joseph M. Betz, et. al. Progress in Development of an Integrated Dietary Supplement Ingredient Database at the NIH Office of Dietary Supplements. Journal of Food Composition Analysis (in press)

# **Methods and Materials**

NHANES 01-02 dietary supplement questionnaire data files and demographic files were used to determine the reported prevalence of beta carotene, folic acid, Vitamins A, B-6, B-12, C, D, E, K, riboflavin, thiamin, niacin, calcium, iron, potassium, phosphorus, copper, selenium, chromium, magnesium, manganese, zinc and iodine in adult MVM products. The NHANES data files link each product reported to individual survey respondents who statistically represent a portion of the population. Nationally representative prevalence was estimated using person-level sampling weights to account for differential probabilities of selection and non-response, post-stratified to US Census Bureau population estimates. Numbers of supplements, respondents and weighted frequencies of use for all 23 nutrients were summed at each % DV level. Multivitamins containing common %DV levels were statistically selected for the %DV study.

A pilot study to assess sample handling, analytical methods and laboratory variability for Vitamin D and 22 other nutrients in MVM was conducted. A total of 8 laboratories participated in this study. One standard reference material and one control MVM product with blind duplicates were sent to the chosen laboratories 5 times to assess between-day and within-day variability. The following information was collected for sample handling: number of pills homogenization method, equipment, and time of homogenization For each nutrient, laboratory in-house quality control information, extraction methods, analytical methods, and results of repeated measurements were recorded. Coefficients of Variance (CV) were analyzed using SAS 9.1(SAS Institute Inc., Cary, NC, USA).

## **Results and Discussion**

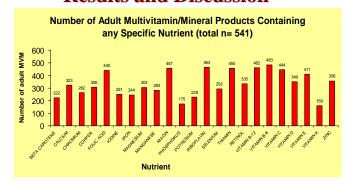


Figure 1: Reported number of adult MVM from NHANES 01-02 containing any specific nutrient. In the NHANES 01-02 survey, more than 1800 adult respondents, representing about 35% of the US adult population, reported taking at least one MVM product during the previous month. Among the total of 2200 supplements taken, about 541 products (24%) were adult MVM formulations. B Vitamins were the most common nutrients in MVM products. Over 80% of adult MVM contained vitamins B-6, B-12, riboflavin, niacin, thiamin, vitamin C and folic acid. Table 1 shows 3 or 4 typical quantities for the 23 nutrients in these adult MVM products. The most common %DV level was 100 for 16 nutrients. The other common levels ranged from 2% to 6666% DV.

Vitamin D provides an example of the analyses done on the other 22 nutrients. A total of 1726 respondents, representing 29% of US adults, took a vitamin D-containing MVM. Of the adult MVM reported in the survey, 349 products contained Vitamin D, in most cases as ergo-calciferol (D2), ranging from 5% to 250% DV (20 International Units (IU) to 1000 IU). More than 88% of respondents who reported taking adult MVM took a MVM containing Vitamin D at 100% DV. There were a total of 258 MVM at this level. Figure 2 shows the distribution of weighted frequency of use vs. %DV levels in MVM containing Vitamin D.

# **Results and Discussion**

Table 1: Common DV Levels (Based on NHANES 01-02 Data) and Weighted Frequency of Use

Nutrient (labeled amount of 100%DV)	1 <sup>st</sup> Common % DV Level	% of weighted frequency of use at 1st Common %DV level	2 <sup>nd</sup> Common % DV Level	% of weighted frequency of use at 2 <sup>nd</sup> Common %DV level	3 <sup>rd</sup> Common % DV Level	% of weighted frequency of u se at 3 <sup>rd</sup> Common %DV level
Beta-carotene (10000IU)	20	59	100	5.02	200	4.37
Calcium (1000mg)	16	33	20	19.35	45	9.91
Chromium (120mcg)	100	40	166	21.46	41	5.42
Copper (2mg)	100	80	175	6.07	50	3.58
Folic Acid (400mcg)	100	90	200	1.97	50	1.87
lodine (150mcg)	100	90	33	1.67	66	1.35
Iron (18mg)	100	69	150	10.86	50	6.23
Magnesium (400mg)	25	67	12	6.72	50	5.66
Manganese (2mg)	100	54	175	10.57	250	10.45
Niacin (20mg)	100	60	200	5.75	500	5.00
Phosphorus (1000mg)	11	46	5	24.37	13	4.56
Potassium (4000mg)	2	67	1	4.82	0.2	3.29
Retinol (5000IU)	80	47	100	23.38	50	3.77
Riboflavin (1.7mg)	100	55	300	7.01	200	3.12
Selenium (70mcg)	28	50	285	12.80	100	9.32
Thiamin (1.5mg)	100	54	300	7.58	6666	3.72
Vitamin B12 (6mcg)	100	43	416	12.55	300	6.42
Vitamin B6 (2mg)	100	43	150	14.82	300	9.73
Vitamin C (60mg)	100	53	200	11.83	833	3.12
Vitamin E (30IU)	100	49	200	15.01	333	6.42
Vitamin D (400IU)	100	88	50	4.42	62.5	2.22
Vitamin K (80mcg)	31	57	12	20.95	100	7.13
Zinc (15mg)	100	81	166	2.05	33	1.50

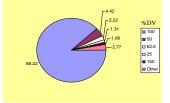


Figure 2. Distribution of weighted frequency of use vs. %DV levels in MVM containing Vitamin D.

Sample handling and analysis results were evaluated. Table I shows the recommended analytical methods for each nutrient. Most vitamins were analyzed by HPLC except for folic and vitamin B-12 which were used for microbiological. Ten of these minerals were analyzed by ICP, expect for iodine, which was analyzed by titration. For the 11 minerals evaluated in this study, analytical CVs (Coefficients of variation) in acceptable laboratories were at or below 10%, sometimes below 5%. For the water soluble vitamins, analytical CVs (between-day variability) in acceptable labs were below 10%, except for Vitamin B12, which had variability as high as 30%. The fat-soluble vitamins had relatively higher variability than the other nutrients. Analytical CVs for alphatocopherol (vitamin E) and vitamin K in acceptable labs were approximately 10%. Variability was higher for beta-carotene, retinol and vitamin D, with analytical CVs between 15 and 20%.

# **Future Plans**

A % DV study based on these NHANES results is underway, which is assessing the systematic relationship of label value vs. analyzed value. Regression analysis will be applied to the analytical results to establish additional estimates for nutrient levels in adult MVM products reported in the NHANES survey.

Subsequent studies are planned for the analysis of children's MVM products and calcium products (including antacids). Nutrients to be analyzed in future studies include: other single and double nutrient supplement products (especially vitamin D products), glucosamine and chondroitin products, and fish oil supplements. When analytical methods and reference materials are available, botanical ingredients will also be studied.

The primary use of this database will be to support research on the US intake of nutrients from supplements and food. The data will be incorporated into a publicly available online database.